UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/084,892	02/27/2002	Shukti Chakravarti	P-CW 4945	1524

23601 7590 11/15/2004

CAMPBELL & FLORES LLP
4370 LA JOLLA VILLAGE DRIVE
7TH FLOOR
SAN DIEGO, CA 92122

EXAMINER	
PONNALURI, PADMASHRI	
ART UNIT	**PAPER NUMBER**
1639	

DATE MAILED: 11/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/084,892	CHAKRAVARTI, SHUKTI	
	Examiner	Art Unit	
	Padmashri Ponnaluri	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 August 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) *1-13 and 16-18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14 and 15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *2/27/02* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *8/14/02*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's election with traverse of group VI, claims 14-15; and election of 'GRO3, HNL, REG1B, Elafin, collagen' as species of IBD genes, in the reply filed on 8/12/04 is acknowledged. The traversal is on the ground(s) that the Office action appears to lack rational for why the restricted groups of inventions satisfy the guidelines; absent a specific showing or rational why each group of inventions are distinct the conclusary statements in the Office action fails to satisfy the Office's action. This is not found persuasive because examiner in the restriction requirement has specifically pointed out how different groups of inventions are restrictable, for example, 'groups I, II, IV, V, VII and VII are all drawn to different methods with different method steps, result in different products/results and discussed how each method is distinct from the other; and different products of groups VI (array) and IX (a pharmaceutical preparation); and group VIII and group VII are related as product and process of making product; group VIII and group IX are related as product and process of use; group III kit' are distinct and restriction is proper between the groups. Applicants have not provided reasons with traversal that any of the groups as restricted are not distinct from each other.

Applicants arguments that 'elected group VI would include art relevant to the claims of groups I-V and VII-IX because at least 25 different IBD genes contained within the array of group VI claims are those genes identified or utilized in the methods of groups I, II, IV, V, VII and VIII and kit of group III.'

Applicants arguments have been considered and are not persuasive, since the nucleic acid array as recited in claim 14 of group VI is not identified in the group I method; and group II is drawn to the use a single gene identified in group I; group III kit includes instructions to identify

the genes involved in IBD, not as the probes which selectively binds to at least 25 IBD genes of elected group VI; group IV method is doing business not relevant to the elected group VI nucleic acid array; group V is drawn to a method of treating a patient do not require the nucleic acid array of elected group VI; and group VII does not require the elected nucleic acid array; and the group VIII pharmaceutical composition uses the product identified by the method of group VII. Thus, restriction between the groups is proper.

Applicants arguments that the search for group VII would include art relevant to the claims of groups I-V, and VII-IX is not persuasive, since these inventions have acquired a separate status in the art as shown by their different classification and/or divergent subject matter. Each of the different methods and products would require completely different searches in the patent and non-patent databases, and there is no expectation that the searches would be coextensive. Therefore, this does create an undue search burden, and restriction for examination purposes as indicated is proper. The search for group VII may come across general references regarding IBD and genes involved in IBD, which may not be useful for each group and however each group as restricted have different limitations (i.e., method limitations) which require different considerations and acquired different status. Does applicants mean that the references which are useful for the elected group VII would be used for all the restricted groups, even though the limitations of elected group 'nucleic acid array probe which selectively binds to at least 25 IBD genes' are not present in the restricted groups I-VI and VIII-IX.

Applicants additionally, argue that group II inventions depends from the group I because these claims include "other IBD genes identified according to the method of claim 1." Therefore at least group I and group II should be rejoined. Applicants arguments have been considered and

are not persuasive, since the group II method uses either known IBD gene or further uses the identified genes by the group I method. Thus, group II method is distinct from the group I method.

Applicants argue that since groups I, II and VII have been classified in the same class and subclass, therefore applicant request rejoinder of the claims of all groups and examination together. Applicant's arguments have been considered and are not persuasive, even though some of the groups are classified in the same class/subclass, this has no effect on the non-patent literature search. Different inventions or groups would require completely different searches in non-patent databases, and there is no exception that the searches would be co-extensive. Thus, restriction between the groups is proper.

Applicants traverse the election of species requirement. To require less genes to be examined than that claimed is improper. Applicant's arguments have been considered and are not persuasive, since the examiner has only made a species election of IBD genes. And examiner has not restricted out the 5 different genes as in applicants arguments. Since the invention as claimed does not recite the IBD genes, and search and examination purpose, a species election of at least 5 genes present in the set of at least 25 IBD genes was requested. And further it is noted that applicant's have not provided sequences of the probes present in the claimed array as requested in the restriction requirement.

Applicants state that if rejoinder is denied for all or some of the restricted claims, applicants respectfully request a "second-eye review" as now implemented under Restriction Practice plan. Applicants request has been noted, however the 'second-pair of eyes' applicants referring to is an internal program, a request cannot be made. If applicants request a review of

the restriction requirement in this application, applicants are requested to file a formal 'Petition requesting reconsideration of restriction requirement.'

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 1-13, 16-18 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 8/12/04.

3. Claims 14-15 are currently being examined in this application.

4. This application is a CIP of 09/694,758, which claims benefit to provisional application 60/160,835, filed on 10/21/99.

Specification

5. The disclosure is objected to because of the following informalities: The specification in page 31 refers to SEQ ID Nos: 1-146, which were not found in the application.
Appropriate correction is required.

6. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: no support for the claim terminology 'selectively hybridize' is found in the specification. The specification in page 31, defines 'specifically hybridizes' which is different from the 'selectively hybridize'. Applicants are requested to point out the support for this limitation.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 14-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

The instant claims briefly recite 'a nucleic acid array comprising a solid support and displayed thereon nucleic acid probes which selectively hybridize to at least 25 different IBD genes.'

The specification has not disclosed nucleic acid probes which specifically hybridize to at least 25 IBD genes. The specification disclosure is narrative and discloses methods for synthesizing oligonucleotide probes. The specification discloses that the invention relates to novel methods for identifying and/or classifying patients with inflammatory bowel disease (IBD). The subject method is based on findings that certain genes are differentially expressed in intestinal tissue of IBD patients compare to with normal cells. Table 1 indicates those sequences which are over or under expressed in a CD or UC derived cells relative to normal cells. The specification discloses that the preferred nucleic acid molecules for use as probes/primers or

antisense molecules can comprise at least about 12, 20, 30, 50, 60, 70, 80, 90 or 100 base pairs in length up to the length of complete gene. The specification discloses that the present invention provides a method for where nucleic acid probes are immobilized on a DNA chip in an organized array, and the chip can hold the nucleic acid probes comprising preferably at least 15 nucleotides and up to all or nearly all of the coding sequence which is complementary to the a portion of the coding sequence of a marker nucleic acid sequence, which nucleic acid is represented in Table 1 [0224].

The specification has not disclosed the probes, which selectively hybridize to IBD genes. The specification discloses all known methods for synthesizing DNA arrays [0228]. The specification has not disclosed the array synthesized using known IBD marker genes as disclosed in table 1. The specification disclosure is narrative and hypothetical and only discloses the known IBD genes. The specification has not disclosed the probe sequences, and by defining that the probe is any 15 mer of the known genes is not sufficient to identify which sequences would selectively hybridize to at least 25 different IBD genes. According to the instant claim, the probe sequence has to selectively hybridize to at least 25 different IBD genes. Further these at least 25 different IBD genes (of the instant claims) need not to be the IBD genes provided in the Table 1 of the specification. And the term 'selectively hybridize' is a functional limitation. And the specification has not disclosed the probe sequences (either 15 mer or upto 100 mer) which selectively hybridize to the IBD genes. And the specification has not disclosed which probe sequences would specifically hybridize to the IBD gene, i.e., which 15 mer of the gene would selectively hybridize to the IBD genes.

The specification does not have any working examples, in which nucleic acid array probes selectively hybridize to at least 25 IBD genes.

With regard to the description requirement, Applicants' attention is directed to The Court of Appeals for the Federal Circuit which held that a "written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398, 1405 (1997), quoting *Fiers v. Revel,* 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) (bracketed material in original)[The claims at issue in *University of California v. Eli Lilly* defined the invention by function of the claimed DNA (encoding insulin)].

Thus, it requires a representative sample of compounds (i.e., sequences) or a showing of sufficient characteristics to demonstrate possession of the claimed invention.

To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention (see MPEP 2163).

The instant specification discloses well known methods to make nucleic acid array, and does not disclose the claimed nucleic acid array probes which selectively hybridize to at least 25 IBD genes.

The disclosure of only a method of making the invention and the function may not be sufficient to support a product claim other than a product-by-process claim. See, e.g., Fiers v. Revel, 984 F.2d at 1169, 25 USPQ2d at 1605; Amgen, 927 F.2d at 1206, 18 USPQ2d at 1021.

An applicant may show possession of an invention by disclosure of drawings or structural chemical formulas that are sufficiently detailed to show that applicant was in possession of the claimed invention as a whole. See, e.g., Vas-Cath, 935 F.2d at 1565, 19 USPQ2d at 1118.

In the present instance, the claimed invention contains no identifying characteristics regarding the nucleic acid probes (no sequences), except they selectively hybridize to at least 25 IBD genes. The specification has not disclosed the term 'selectively hybridize', and the genes and accession numbers in table 1 are clearly not representative of the scope of the nucleic acid array of the presently claimed invention.

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 14-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 14 is vague and indefinite by reciting 'array of nucleic acid probes which selectively hybridize to at least 25 IBD genes.' The term 'selectively hybridize' is a relative term, and it is not clear selective to which genes, the probes hybridize to the IBD genes. And the specification has no definition for 'selectively hybridize.'

Claim Rejections - 35 USC § 102 and 103

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. Claims 14-15 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Dickgraefe et al (Gastroenterology, vol. 114, no. 4, G3954).

The instant claims briefly recite 'a nucleic acid array comprising a solid support and displayed thereon nucleic acid probes which selectively hybridize to at least 25 different IBD genes.'

Dieckgraefe et al disclose characterization of mucosal gene expression in Inflammatory bowel disease (IBD) by direct hybridization to massive parallel oligonucleotide arrays. The reference discloses that parallel or high throughput methods of measuring gene expression have been recently developed which allow concurrent measurement of the expression pattern of a large number of genes. The reference discloses the use of Genechip (refers to the solid support chip of the instant claims) expression monitoring system to examine mucosal gene expression in ulcerative colitis, Crohn's colitis to identify genotypes associated with particular disease. The reference discloses that RNA isolated from the mucosal colonial specimens was used to generate hybridization probes. The reference further discloses that light directed solid phase (refers to the support of the instant claims) combinatorial chemistry was used to generate oligonucleotide

probe arrays (refers to nucleic acid probes of the instant claim array) which provide representation of nearly 7000 human cDNA and EST sequences, which would refer to the instant claim probes which selectively hybridize to at least 25 IBD genes. The reference further discloses that hybridization to the oligonucleotide arrays was sensitive, specific and reproducible.

Alternatively, the claimed invention further differs from the prior art teachings only by the recitation of 'probes which selectively hybridize to at least 25 IBD genes' and the solid support is either paper, membranes, filter, chips, pins and glass. The claimed invention appears to be the same or obvious variations of the reference teachings, absent a showing of unobvious differences. The office does not have the facilities and resources to provide the factual evidence needed in order to determine and/or compare the specific activities of the instant versus the reference probes, and the solid support in the reference array. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed nucleic acid probes are different from the one taught by prior art and to establish the patentable differences. See in re Best 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray 10 USPQ2d 1922(PTO Bd.Pat. App. & Int. 1989).

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Padmashri Ponnaluri whose telephone number is 571-272-0809.

The examiner is on Increased Flex Schedule and can normally be reached on Monday through Friday between 7 AM and 3.30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Padmashri Ponnaluri
Primary Examiner
Art Unit 1639

10 November 2004

PADMASHRI PONNALURI
PRIMARY EXAMINER